

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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**IN RE: PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION**

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**MDL No. 1456**  
C.A. No. 01-12257-PBS

**THIS DOCUMENT PERTAINS TO:  
ALL CLASS ACTIONS**

Judge Patti B. Saris

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**CLASS PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT  
OF MOTION FOR SUMMARY JUDGMENT ON  
DEFENDANTS' AFFIRMATIVE DEFENSES**

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## I. INTRODUCTION

Plaintiffs submit this brief in support of their motion for summary judgment dismissing the affirmative defenses raised by the Track 1 Defendants, namely, AstraZeneca Pharmaceuticals LP (“AstraZeneca”), GlaxoSmithKline (“GSK”), Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutical Products, L.P., McNeil-PPC, Inc., and Ortho Biotech Products, L.P. (collectively, “J&J”), Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation and Apothecon, Inc. (collectively “BMS”), Schering-Plough Corporation (“Schering”) and Warrick Pharmaceuticals Corporation (“Warrick”), in their respective answers [Doc. Nos. 1851, 1848, 1847, 1850, 1855 and 1856, respectively] to Plaintiffs’ Third Amended Master Consolidated Class Action Complaint (“TAMCC”) [Doc. Nos. 1781-1781].<sup>1</sup> It is obvious from the respective answers of the Track 1 Defendants that they employed a “kitchen sink” approach to their claimed “affirmative defenses” in this case. The intent of this Motion is to weed through these many baseless claims to separate the chaff from the wheat in advance of trial, and winnow down the claimed defenses to only those that (1) truly apply to this case, and (2) have some evidentiary support. While Plaintiffs realize the task may appear overwhelming at first blush, in reality it will not be very difficult for this Court to determine which, if any, affirmative defenses truly generate “trial worthy issue[s].” *Stevens v. Cedarapids, Inc.*, No. Civ.

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<sup>1</sup> Defendants have yet to respond to the Fourth Amended Master Consolidated Class Action Complaint (“FAMCC”) [Doc. Nos. 2171-2176], filed by Plaintiffs on March 2, 2006. However, since motions for summary judgment are due on March 15, 2006, prior to the date on which Defendants’ answers to the FAMCC are due, Plaintiffs address the affirmative defenses raised in response to the previously filed TAMCC. However, since Plaintiffs’ general allegations asserted in the TAMCC remain the same in the FAMCC, it is reasonable to anticipate that Defendants’ affirmative defenses likewise will not change.

04-89-B-W, 2006 WL 412192, at \*4 (D. Me. Feb. 17, 2006) (granting all but one of plaintiff's motions for summary judgment on defendant's affirmative defenses).

Collectively, Defendants raise a total of fifty eight (58) separate "affirmative defenses,"<sup>2</sup> some of which contain multiple asserted theories of defense.<sup>3</sup> There are four (4) general reasons why the claimed affirmative defenses should be dismissed. First, Plaintiffs' claims giving rise to certain of the defenses either have been dismissed by the Court or withdrawn by Plaintiff. Those defenses are now moot but are still asserted by Defendants. Second, prior decisions of this Court have addressed (and rejected) certain matters raised by Defendants, as affirmative defenses. Such prior rulings – the law of this case – renders these defenses legally insufficient at this point. Third, many claims are properly dismissed because they are not "defenses" at all, or appropriate defenses to the trial claims of Class Plaintiffs. Lastly, Defendants cannot meet their burden of establishing "genuine issues of material fact" as to the elements of the remaining defenses. For these reasons, as detailed below, this Court should grant summary judgment as to some or all of the affirmative defenses.

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<sup>2</sup> While the Defendants label each of their claims "affirmative defenses," most of their claims are not legal "defenses" at all to Plaintiffs' claims. Rather, they largely consist of defense arguments about facts and law and/or generalized statements about factual and legal propositions, which have no bearing on the triable issues in this case.

<sup>3</sup> For ease of reference, Plaintiffs have created a chart (Exhibit "A" hereto) listing all affirmative defenses of the Track 1 Defendants. Because AstraZeneca alleged the most affirmative defenses, and is the first Track 1 Defendant scheduled for trial (September 11, 2006), the references to affirmative defense in this Brief cite AstraZeneca's particular affirmative defense; The chart then lists the other Track 1 Defendants who alleged the same affirmative defense and at which number in their respective Answers.

## **II. ARGUMENT**

### **A. THE APPLICABLE STANDARD FOR SUMMARY JUDGMENT REQUIRES THE DISMISSAL OF ALL OF DEFENDANTS' AFFIRMATIVE DEFENSES.**

The general standard for summary judgment under FED. R. CIV. P. 56 is set forth in Plaintiffs' Motion for Partial Summary Judgment Respecting AstraZeneca's Guilty Plea on Free Sample Conduct, which is incorporated by reference thereto. Respecting the instant Motion, which seeks dismissal of all of Defendants' affirmative defenses, "the usual rule, honored by Massachusetts as by most jurisdictions, is to place the burden of proving affirmative defenses on the party asserting them." *U.S. Liability Ins. Co. v. Selman*, 70 F.3d 684, 691 (1<sup>st</sup> Cir. 1995). Where the plaintiff/movant seeks summary judgment respecting a defendant/non-movant's assertion of an affirmative defense, defendant "must make 'a showing sufficient' to establish the existence of the essential elements of the claim." *John Hancock Life Ins. Co. v. Abbott Labs.*, No. Civ. A. 03-12501-DPW, 2005 WL 2323166, at \*27 (D. Mass. Sept. 16, 2005) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). See also *Stevens, supra*, 2006 WL 412192 (finding that defendants failed to come forward with sufficient trial worthy issue as to all but one of their affirmative defenses, warranting summary judgment in favor of plaintiff). Here, Defendants cannot sustain their respective burdens to establish each and every element, on which they bear the burden of proof, of their pled "affirmative defenses." This failure to demonstrate a "trial worthy issue" warrants summary judgment and the dismissal of these claimed defenses as a matter of law.

**B. SUMMARY JUDGMENT IS APPROPRIATE AS TO ALL AFFIRMATIVE DEFENSES RELATING TO PLAINTIFFS' CLAIMS EITHER HAVE BEEN DISMISSED BY THE COURT OR WITHDRAWN BY PLAINTIFFS.**

**1. Affirmative Defenses As to Plaintiffs' RICO Claims.**

Four affirmative defenses pertain to Plaintiffs' claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968. *See AstraZeneca Aff. Defs. 20, 21, 22 and 23.* This Court has held that Plaintiffs could not establish a RICO enterprise, as required under the statute, respecting the alleged AWP Enterprises (involving the Defendants and medical providers), the alleged Third Party Payor/Victim Enterprises and the alleged Defendant-Publisher Enterprises.<sup>4</sup> Without any triable RICO claims (Counts I and II of the FAMCC), affirmative defenses related to RICO allegations should be stricken (AstraZeneca Aff. Defs. 20, 21, 22 and 23 and the corresponding defenses of other defendants).<sup>5</sup>

**2. Affirmative Defenses As to Plaintiffs' Antitrust Claims.**

Plaintiffs' antitrust claims, under the Sherman Act 15 U.S.C. § 1 and certain state antitrust acts, were limited solely to Plaintiffs' claims as to the Together RX Card in the Second Amended Master Consolidated Class Action Complaint. These claims were dropped, and were not included in either the TAMCC or the FAMCC. Defendants' affirmative defenses relating to such antitrust claims (AstraZeneca Aff. Defs. 36, 37, 39, 40, 41, 42, and 43) should be dismissed.

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<sup>4</sup> Only the alleged enterprise between Defendants and the pharmacy benefit managers ("PBMs") is left. With respect to this remaining RICO claim, the Court denied class certification on grounds that the predominance requirement was not satisfied. *See In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 263 F. Supp.2d 172, 181-86 (D. Mass. 2003); *In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 307 F. Supp.2d 196, 203-05 (D. Mass. 2004). *See In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005). This Court is not asserted by Class 1 and 2 and should be stricken.

<sup>5</sup> The chart at Exhibit "A" lists all the defenses as they match up to those of AstraZeneca.

**C. AFFIRMATIVE DEFENSES THAT HAVE BEEN RULED UPON PREVIOUSLY SHOULD BE DISMISSED.**

**1. “Affirmative Defenses” Alleging “Failure To State a Claim Upon Which Relief Can Be Granted.”**

Defendants’ affirmative defense that Plaintiffs failed to state a claim upon which relief can be granted was rejected by this Court in deciding defendants 12(b)(6) Motions to Dismiss. *See In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 263 F. Supp.2d 172, 181-86 (D. Mass. 2003); *In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 307 F. Supp.2d 196, 203-05 (D. Mass. 2004). Moreover, this type of allegation, which merely rephrases the standard for evaluating a motion to dismiss under Rule 12(b)(6), “is not an affirmative defense which adds substance to the litigation; it is clutter.” *Surface Shields, Inc. v. Poly-Tak Protection Systems*, 213 F.R.D. 307, 308 (N.D. Ill. 2003). Therefore, AstraZeneca Aff. Def. 1 should be dismissed.

**2. Affirmative Defenses Alleging that Plaintiffs’ Claims Are Barred by the “Political Question” and “Separation of Powers” Doctrines.**

In its Memorandum and Order of May 13, 2003, this Court denied Defendants’ Motion to Dismiss respecting Defendants’ “[d]rawing on the policies underpinning the political question doctrine, and urging ‘prudential abstention.’” 263 F. Supp.2d at 180. This Court also rejected Defendants’ argument that Congress “acceded to this widespread pricing and reporting practice,” by virtue of legislative hearings and statements on AWPs, which allegedly demonstrated that Congress knew that the AWPs that Defendants were reporting represented only an “undiscounted sticker price” that has no direct relation to the actual average price they charge for their drugs.” *Id.* Therefore, AstraZeneca Aff. Def. 2 should be dismissed.

**3. Affirmative Defenses Alleging that Plaintiffs' Claims Are Barred by the "Filed Rate Doctrine."**

Also in its May 13, 2003 Memorandum and Order, this Court rejected Defendants' contention that the "Filed Rate Doctrine" was applicable to this case. *Id.* at 192. Thus, AstraZeneca Aff. Def. 3 should be dismissed.

**4. Affirmative Defenses Alleging that Plaintiffs' Claims Are Barred by the "State Action Doctrine."**

This Court addressed and found to be baseless defendants' allegation in their Motions to Dismiss that the so-called "government action" doctrine barred Plaintiffs' claims. BMS alleges in its Fifth Affirmative Defense that Plaintiffs' claims are barred by the "state action doctrine." The "government action doctrine" and the "state action doctrine" are the same. In fact, the case cited respecting the putative "government action doctrine" in this Court's May 13, 2003 Memorandum and Order, *Sandy River Nursing Care v. Aetna Cas.*, 985 F.2d 1138, 1143-44 (1<sup>st</sup> Cir. 1993), actually refers to the doctrine as the "state action doctrine." 263 F. Supp.2d at 192. Thus, BMS Aff. Def. 5 should be dismissed.

**5. Affirmative Defenses Alleging that Plaintiffs' Claims Are Barred by the "Noerr-Pennington Doctrine."**

The *Noerr-Pennington* doctrine immunizes persons from antitrust liability for harm that results directly from government-petitioning activity. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). As stated above in section IIB2, antitrust claims are out of the case, rendering *Noerr-Pennington* irrelevant. Further, even if relevant, the doctrine only immunizes valid "petitioning" activity, of which there is no evidence in this case.

Lastly, in rejecting the “government action doctrine,” this Court cited the *Noerr* decision and noted that “plaintiffs do not claim that the harm they suffer stems from the AWP system as Congress has established it, but rather from the defendants’ fraudulent statements about their average wholesale prices.” 263 F. Supp.2d at 192. For all these reasons, AstraZeneca Aff. Def. 7 should be dismissed.

**6. Affirmative Defenses Alleging that Plaintiffs’ Claims Are Preempted by the Medicare Act, the Medicaid Act and/or ERISA.**

In May of 2003, this Court conducted full analyses of the Defendants’ arguments respecting preemption of Plaintiffs’ claims, including under the federal Medicare Act and the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1144(a) (“ERISA”). 263 F. Supp.2d at 186-92. Respecting Medicare, this Court held that there was no actual conflict between the maintenance of the state consumer fraud claims and the operation of the federal Medicare program, noting that “CMS does not make a discretionary judgment with respect to the statutorily defined Medicare Part B reimbursement rates, and does not approve AWPs” and that therefore, “the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs’ harm.” *Id.* at 188-89. The Court also held that there was no ERISA preemption, “[b]ecause the consumer protection statutes do not have a sufficient ‘connection to’ the employee benefit plans and do not refer to ERISA plans.” *Id.* at 192. Thus, AstraZeneca Aff. Def. 10 should be dismissed.

**7. Affirmative Defenses Alleging that Plaintiffs' Claims Are Preempted by the "Dormant Commerce Clause" of the United States Constitution.**

If Defendants wanted to press a claimed "affirmative defense" alleging that Plaintiffs' claims were preempted by the dormant Commerce Clause of the United States Constitution, they should have done so in conjunction with their other unmeritorious preemption arguments. That they chose not to do so in the context of their Motions to Dismiss speaks volumes about the merit of the claim now.

Without any guidance from Defendants as to how they believe this concept might apply to the case, Plaintiffs turn to a recent decision of the First Circuit addressing both alleged preemption under ERISA and under the dormant Commerce Clause for the appropriate standard:

The Commerce Clause provides that Congress shall have the power "to regulate Commerce ... among the several States." U.S. Const. art. I, § 8, cl. 3. It has long been understood, however, that this affirmative grant of authority to Congress necessarily encompasses a limitation on the power of states to enact legislation that burdens the flow of interstate commerce. This restriction on the states, known as the dormant Commerce Clause, is not absolute and in the absence of conflicting legislation by Congress, "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected."

*Pharmaceutical Care Management Ass'n v. Rowe*, 429 F.3d 294, 310-11 (1<sup>st</sup> Cir. 2005) (quoting *Maine v. Taylor*, 477 U.S. 131, 138 (1986)).<sup>6</sup> For Defendants to argue that the states' enactment

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<sup>6</sup> In rejecting both the ERISA preemption and the dormant Commerce Clause preemption arguments of plaintiff, the First Circuit held that "[w]hen measuring PCMA's concern about its members' profits against the increased access to prescription drugs for Maine citizens, the local benefits clearly outweigh any incidental burden on interstate commerce." 429 F.3d at 313. Similarly, in the instant case, the interests of consumers in not being defrauded and forced to overpay for their cancer drugs far outweighs the interests of the pharmaceutical companies in maintaining their profits.

of consumer fraud laws would burden the flow of interstate commerce is indefensible. Respectfully, Plaintiffs submit that this Court should deny claims of “Dormant Commerce Clause” preemption consistent its prior ruling on Medicare and ERISA preemption. Therefore, AstraZeneca Aff. Def. 11 should be dismissed.

**8. Affirmative Defenses Alleging that Plaintiffs Failed To Plead Fraud with Particularity under Rule 9(b).**

Failure to plead fraud with the requisite particularity under Rule 9(b) was addressed in May 2003 when this Court held that, “in light of the detailed fraudulent scheme alleged, the plaintiffs’ allegations were sufficient with respect to ‘any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug.’” 307 F. Supp.2d at 208 (quoting *Pharm. I*, 263 F. Supp.2d at 194). This Court revisited the issue in February 2004 when it held that, “[w]ith respect to most Defendants, the Court finds that Plaintiffs in the AMCC have pled allegations concerning the fraudulent scheme with enough specificity to comply with the requirements of Rules 9(b) and 8(a).” *Id.* The TAMCC and FAMCC have only greater particularized claims as to the current Defendants. AstraZeneca Aff. Def. 16 should be dismissed.

**9. The Affirmative Defense Alleging that Plaintiff Failed To Plead Civil Conspiracy with Particularity.**

Like their residual “preemption” argument under the dormant Commerce Clause, Defendants should have reserved a challenge to the Plaintiffs’ claims of civil conspiracy. Likewise, such “9(b) claim” – *i.e.* AstraZeneca Aff. Def. 17 – should be dismissed.

**10. Affirmative Defenses Alleging Lack of Standing To Bring Consumer Protection Claims Under State Statutes.**

This Court already has determined that Plaintiffs have standing to bring their claims under the forty-one (41) state consumer protection statutes included in the certification of Class 1, and under Massachusetts law as to Classes 2 and 3. *In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, 230 F.R.D. 61, 79 (D. Mass. 2005) (“Standing frequently appears as a threshold requirement for the maintenance of federal class actions and must be considered in addition to the requirements of Rule 23 when deciding whether a particular action may be certified.”) (internal quotations omitted). See also Consolidated Order re: Motion for Class Certification, dated January 30, 2006, *In re Pharmaceutical Indus. Aver. Wholesale Price Litig.*, MDL 1456, 2006 WL 235066 (Jan. 30, 2006) (“Class Certification Order”). AstraZeneca Aff. Def. 30 should be dismissed.

**11. Affirmative Defenses Alleging that the Action Cannot Be Maintained As a Class Action Should Be Dismissed.**

The aforesaid Class Certification Order resolves AstraZeneca Aff. Def. 35. See, id.

**12. Affirmative Defenses Alleging that Plaintiffs’ Claims Are Barred by a Lack of Causation Because Defendants’ Conduct Allegedly Did Not Proximately Cause Plaintiffs’ Injuries and/or Because Plaintiffs’ Injuries Allegedly Resulted from Intervening or Superceding Conduct of Third Parties.**

In deciding Defendants’ motions to dismiss, this Court already considered and rejected Defendants’ lack of causation arguments finding that they were “not persuasive.” 307 F. Supp.2d at 207-08 (“In the private, end-payor context, the harm alleged by Defendants’ alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named

drugs based upon AWP's. Similar arguments about intervening causes between the setting of an AWP by a defendant and injuries to plans and individual co-payors were recently rejected as ‘border[ing] on the frivolous.’”) (citing *In re Lupron Marketing and Sales Practices Litig.*, 295 F. Supp.2d 148, 175 (D. Mass. 2003) (Stearns, J.)). For this reason, and a lack of evidentiary support for the claims, AstraZeneca Aff. Defs. 15, 27 and 48 should be dismissed.

**13. Affirmative Defenses Alleging that Any Fraudulent Statements Made by Defendants Were Not Consumer-Oriented as Required Under Certain Consumer Protection Statutes, Including New York.**

New York's highest court has held that, when making a claim under New York's consumer protection statute, N.Y. GEN. BUS. L. § 349, a plaintiff “must charge conduct of the defendant that is consumer-oriented,” and to show such conduct is consumer-oriented, plaintiff “must demonstrate that the acts or practices have a broader impact on consumers at large.” *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 25, 623 N.Y.S.2d 529, 532, 647 N.E.2d 741, 744 (1995). This Court previously ruled that the harm caused by Defendants' statements about the AWPs for their drugs were “visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs based upon AWP's.” 307 F. Supp.2d at 207-08. Indeed, Defendants knew that the success of their fraudulent scheme and conspiracy to inflate the AWPs of their drugs, to deeply discount the price of their drugs to providers, and to market the resultant spread or profit from this pricing manipulation in order to increase and/or maintain market share was dependent upon Medicare beneficiaries, Medigap carriers and other insurance carriers all paying the overcharge resulting from the AWP inflation. This Court also recognized that Plaintiffs are “pressing only the theory that defendants intentionally made fraudulent misrepresentations of AWP” and that “consumers (elderly people

with cancer or another serious disease) make a percentage co-payment based upon the stated AWP.” 230 F.R.D. at 85. Thus, there is no “genuine issue” that Defendants’ fraudulent statements about their AWPs were consumer-oriented. *See also Makuch v. New York Central Mutual Fire Ins. Co.*, 12 A.D.3d 1110, 1111, 785 N.Y.S.2d 236, 238 (App. Div. 2004) (holding that allegations that forms making up plaintiffs’ insurance policy were standard and regularly used by defendant are sufficient to support the allegation that defendants’ actions were consumer-oriented under N.Y. GEN. BUS. L. § 349). Therefore, AstraZeneca Aff. Def. 32 should be dismissed.

**D. AFFIRMATIVE DEFENSES WHICH ARE NOT PROPER AFFIRMATIVE DEFENSES SHOULD BE DISMISSED.**

Rule 8(c) of the Federal Rules of Civil Procedure sets forth the types of defenses which are properly set forth as affirmative defenses. The Rule provides:

**(c) Affirmative Defenses.** In pleading to a preceding pleading, a party shall set forth affirmatively accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, statute of limitations, waiver, and any other matter constituting an avoidance or affirmative defense. When a party has mistakenly designated a defense as a counterclaim or a counterclaim as a defense, the court on terms, if justice so requires, shall treat the pleading as if there had been a proper designation.

FED. R. CIV. P. 8(c). Certain “defenses” set forth by Defendants are not cognizable as “affirmative defenses” under Rule 8(c), and therefore should not have been pled as affirmative defenses to the Plaintiffs’ claims in this case. Accordingly, the following claims of Defendants should be dismissed.

**1. Generalized “Affirmative Defenses” Attempting To Incorporate Affirmative Defenses Pled by Other Defendants**

Defendants are all represented by competent counsel. Thus, if any Defendant had wanted to raise an affirmative defense to the Complaint, they could have (and should have) do so. Nonspecific incorporation of other parties’ pleadings are not permissible. Moreover, all Track 1 Defendants have had ample time to seek leave to amend their answers under Rule 15 of the Federal Rules of Civil Procedure if they desired to add specific affirmative defense(s) which they neglected to affirmatively plead (but which their co-defendants had). *See Espinosa v. Sisters of Providence Health System*, 227 F.R.D. 24 (D. Mass. 2005) (in order to add additional affirmative defenses long after answers filed defendants sought leave to amend under Rule 15).<sup>7</sup> Having failed to do so, AstraZeneca Aff. Def. 56 should be dismissed. Also, worthy Defendants like BMS, who alleged far fewer affirmative defenses than any other Defendant – fifteen (15) as compared to fifty-seven (57) by AstraZeneca and J&J and fifty-six (56) by GSK – should be precluded from attempting to adopt dozens of unpled affirmative defenses at trial. *See* BMS Aff. Def. 15.

**2. “Affirmative Defenses” Reserving the Right to Amend Answers To Plead Other Affirmative Defenses At A Later Date**

The AstraZeneca trial is set for September 11. *See* CMO 20, at ¶ 12. Defendants cannot continue to add affirmative defenses up until the eve of trial. According to Rule 8(c), “any

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<sup>7</sup> *See U.S. General, Inc. v. City of Joliet*, 598 F.2d 1050, 1051-52 (7<sup>th</sup> Cir. 1979) (commenting on a party’s non-compliance with Rule 8(a) and (e) and noting that their claim “appea[red] to be a legal bouillabaisse with bits of [several different claims]... all stirred and served as one count.”). *See also Iowa Health System v. Trinity Health Corp.*, 177 F. Supp.2d 897, 905 (N.D. Iowa 2001) (same).

matter constituting an avoidance or affirmative defense’ is generally deemed waived unless raised in an answer.” *Espinosa*, 227 F.R.D. at 26 (holding as to certain affirmative defenses that defendants could not amend their answers to assert same as defendants failed to offer any reason for delay and plaintiffs would be unduly prejudiced). If, at this juncture, Defendants are unwilling or unable to articulate any further affirmative defenses, they should be precluded. Therefore, AstraZeneca Aff. Def. 57 should be dismissed.

### **3. “Affirmative Defenses” Consisting of Factual Denials of Plaintiffs’ Claims**

Certain “affirmative defenses” consist purely of factual denials of Plaintiffs’ allegations, and thus are not “defenses” at all. For instance, Defendants contend that Plaintiffs’ claims are barred because Defendants allegedly did not make false statements to Plaintiffs, because Defendants allegedly did not conspire with any other entity or engage in conduct in violation of state or federal law, and Defendants’ conduct allegedly was not “deceptive,” “misleading,” “unlawful” or “illegal.” They also urge that Plaintiffs do not have valid consumer protection claims under various state statutes. Additionally, Defendants deny (in myriad ways) that Plaintiffs suffered any injury or damage. For example, they argue that TPPs were not injured because they allegedly “passed on” the overcharges to consumers through higher insurance co-pays and premiums; alternatively, they argue that consumers were not injured because the overcharges were not “passed on,” but were absorbed by the direct purchasers. Defendants also allege that Plaintiffs’ claims are insufficient to warrant recovery of attorney’s fees, treble damages, legal fees, and punitive damages. Lastly, Defendants claim that Plaintiffs are precluded from obtaining injunctive or equitable relief because there is a remedy available at law

or the need for such relief allegedly has been obviated by the passage of the 2003 Medicare reform legislation.

None of these contentions constitute cognizable affirmative defenses under Rule 8(c) – they are simply general denials under Rule 8(b). 5 Wright & Miller, Fed. Prac. and Proc. § 1270 (Rule 8(c) “deals with affirmative defenses and should be read in conjunction with, and distinguished from, Rule 8(b), which deals with denials or negative defenses that directly contradict elements of the plaintiff’s claim for relief.”). *See Gilbert v. Eli Lilly & Co., Inc.*, 56 F.R.D. 116, 125 (D.P.R. 1972) (distinguishing negative defense/denial from affirmative defense).

*See also Amco Ukrservice & Prompriladamco v. American Meter Co.*, No. Civ.A. 00-2638, 2005 WL 1541029 at \*6 (E.D. Pa. June 25, 2005) ((distinguishing “affirmative defenses from other denials by the fact that ‘affirmative defense[s] will require the averment of facts extrinsic to the plaintiff’s claim for relief’”) (citation omitted)). Therefore, AstraZeneca Aff. Defs. 4, 18, 19, 26, 28, 29, 33, 44, 45, 47, 52, 53, 54 and 55, all improperly couched as affirmative defenses, should be dismissed.

**E. AFFIRMATIVE DEFENSES AS TO WHICH DEFENDANTS CANNOT ESTABLISH A GENUINE ISSUE OF MATERIAL FACT AS TO ALL ESSENTIAL ELEMENTS OF THE DEFENSES SHOULD BE DISMISSED.**

**1. Affirmative Defenses Contending that Plaintiffs’ Claims Are Barred As a Result of Plaintiffs’ Action or Inaction.**

a. The Statute of Limitations

In a case involving consumer fraud claims, federal courts in Massachusetts apply the Massachusetts statute of limitations and concomitant tolling and discovery rules.

A federal court applies the procedural rules of the state in which it sits. *Hemric v. Reed & Prince Mfg. Co.*, 739 F.2d 1, 2 (1st Cir. 1984). Massachusetts long has considered statutes of limitations to

be procedural, not substantive, in nature. *Hemric*, 739 F.2d at 2; *Brown v. Great Am. Indem. Co.*, 9 N.E.2d 547, 549 (Mass. 1937). Thus, the Massachusetts statute of limitations applies.

*Rhode Island Depositors Economic Protection Corp. v. Hayes*, Civ. A. No. 92-10162-Z, 1994 WL 62165, at \*4 (D. Mass. Jan. 25, 1994). The statute of limitations on a consumer fraud claim in Massachusetts is four years. See MASS. GEN. L. ch. 260, § 5A. Under the Massachusetts discovery rule, “a cause of action accrues when a person (1) knows or has sufficient notice that s/he was harmed; and (2) knows or has sufficient notice of the cause of the harm.” *Lareau v. Page*, 39 F.3d 384, 388 (1<sup>st</sup> Cir. 1994). Plaintiffs contend that the statute of limitations was tolled by Defendants’ concealment of the fraudulent scheme and conspiracy which Defendants created, and that such concealment was an integral part of the fraud without which the scheme could not have succeeded.

As noted by the federal government in its Sentencing Memorandum filed in the case *United States of America v. TAP Pharmaceutical Products, Inc.*, No. 01-CR-10354-WGY (D. Mass.), AstraZeneca concealed both its fraudulent marketing and that of its competitor, TAP Pharmaceutical Products, Inc. (“TAP”):

[I]n 1995, TAP, in a moment of delicious irony, accused its competitor, [AstraZeneca], the manufacturer of Zoladex, with providing inducements to physicians in violation of the Medicare fraud and abuse laws, to include the fact that employees of the competitor were giving free samples to doctors to encourage them to switch from Lupron to Zoladex. [AstraZeneca], in turn, accused TAP of the very same conduct. Top employees from the two companies met in a summit meeting to discuss this exchange of criminal allegations. Did the serious allegations curb TAP’s [or AstraZeneca’s] conduct? Did TAP [or AstraZeneca], aware of allegations that its employees had engaged in criminal conduct, undertake expeditiously to stop the behavior, to train its employees in the rules and to enforce their adherence to the rules? Did either company, in possession of information that a competitor was

violating the rules, report the conduct to prosecutive authorities in an effort to clean up the industry? Unfortunately, the answer to all of these questions is no: TAP [and AstraZeneca], cognizant of the rules and having been accused of violations, simply carried on [their] business as it always had, full criminal speed ahead.

*See* Sentencing Memorandum of the United States, attached as Exhibit “B,” at pp. 62-63.

Because of the self-concealing nature of the fraud committed by AstraZeneca and the other Track 1 Defendants, Plaintiffs did not know (and could not have known) about the drug companies’ fraudulent scheme and conspiracy until, at the earliest time, the companies began pleading guilty to federal criminal charges concerning their fraudulent marketing tactics. *See* Plaintiffs’ Motion for Partial Summary Judgment respecting AstraZeneca’s guilty plea. The first guilty plea occurred when TAP pled guilty to a conspiracy to violate the PDMA in October 2001. The instant action was filed on December 19, 2001. Thus, the claims of Class Plaintiffs were timely filed, and AstraZeneca Aff. Def. 13 (respecting the statute of limitations) should be dismissed.

b. The Statute of Repose.

Unlike many claims in Massachusetts, like those in tort arising from improvements to real property (MASS. GEN. L. ch. 260, § 2B), consumer protection actions do not have a statute of repose. They have only a statute of limitations.<sup>8</sup> *See* MASS. GEN. L. ch. 260, § 5A. Thus, AstraZeneca Aff. Def. 13 (respecting the statute of repose) should be dismissed.

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<sup>8</sup> ““Unlike a statute of limitations, which bars a cause of action if not brought within a certain time period, a statute of repose prevents a cause of action from arising after a certain period. The bar of a statute of repose is absolute, whereas the bar of a statute of limitations is conditional.”” *Agri-Mark, Inc. v. Niro, Inc.*, 214 F. Supp.2d 33 (D. Mass. 2002) (quoting *James Ferrera & Sons, Inc. v. Samuels*, 21 Mass.App.Ct. 170, 486 N.E.2d 58, 61 (1985) (citation omitted)).

c. Laches.

“The equitable defense of laches will bar a party from asserting a claim if the party so unreasonably delayed in bringing the claim that it caused some injury or prejudice to the defendant.” *Errichetti v. Massachusetts Water Resources Authority*, 300 F. Supp.2d 270, 275 n.7 (D. Mass. 2004) (quoting *Polaroid Corp. v. The Travelers Indemnity Co.*, 414 Mass. 747, 759-60, 610 N.E.2d 912 (1993)). As set forth above, Plaintiffs did not unreasonably delay in bringing their claims. Plaintiffs did not know (and could not have known) of the fraudulent marketing scheme and conspiracy employed by Defendants until the same became public with the first guilty plea by TAP. Thus, AstraZeneca Aff. Def. 13 (respecting laches) should be dismissed.

d. Waiver.

“Waiver is ‘the voluntary and intentional relinquishment of a known right’ which is ‘determined from all of the facts and circumstances surrounding each case.’ *Alan Corp. v. Int'l Surplus Lines Ins. Co.*, 823 F. Supp. 33, 42 (D. Mass. 1993) (Gorton, J.) (citations omitted). None of the Defendants specify what “known right” it is that the Plaintiffs allegedly “voluntarily and intentionally relinquished” and in what manner.<sup>9</sup> The absence of a *prima facie* showing that waiver is a defense to the claims raised, and the lack of evidentiary support for the same, warrant summary judgment as AstraZeneca Aff. Def. 13.

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<sup>9</sup> Assuming Defendants contend that Plaintiffs continued receipt of and payment for their cancer medications constitutes waiver, the argument is dealt with below, at section (E)(1)(i).

e. Estoppel

The elements of an equitable estoppel claim are:

- 1) a representation or conduct amounting to a representation intended to induce a course of conduct on the part of the person to whom the representation is made; 2) an act or omission resulting from the representation, whether actual or by conduct, by the person to whom the representation is made; and 3) detriment to such person as a consequence of the act or omission.

*Hoppe v. Baxter Healthcare Corp.*, 878 F. Supp. 303, 312-13 (D. Mass. 1995). *See also Dunkin' Donuts Inc. v. Gav-Stra Donuts, Inc.*, 139 F. Supp.2d 147, 157 (D. Mass. 2001). No Defendant has put forth specific evidence showing conduct or statements by Plaintiffs that induced Defendants to act or not act, nor any detriment which Defendants allegedly suffered therefrom. AstraZeneca Aff. Def. 13 should thus be dismissed.

f. Unclean Hands or In Pari Delicto

The affirmative defense of unclean hands arises from the equitable maxim, “he who comes into equity must come with clean hands.” It prevents one who is ‘tainted with inequitableness or bad faith relative to matter in which he seeks relief’ from obtaining relief from a court of equity.” *Trustees of Columbia Univ. v. Roche Diagnostics, GmbH*, 272 F. Supp.2d 90, 112 (D. Mass. 2002) (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)). No Defendant has alleged any conduct by the Plaintiffs which would come close to bad faith. Certainly, the cancer patients in the Class have done nothing which could cause them to become tainted. Additionally, “the unclean hands doctrine is a double-edged sword: the party that asserts the defense cannot itself have materially

soiled hands.” *Oxford Global Resources, Inc. v. Guerriero*, No. Civ. A. 03-12078-DPW, 2003 WL 23112398, at \*13 (D. Mass. Dec. 30, 2003) (citing *Leo Feist, Inc. v. Young*, 138 F.2d 972, 975 (7<sup>th</sup> Cir. 1943)). In view of Defendants’ unlawful conduct, including the criminal plea of AstraZeneca to part of the conduct at issue in this case, Defendants cannot establish that do not have unclean hands. Therefore, AstraZeneca Aff. Def. 34 should be dismissed.

g. Failure to Join Indispensable Parties

No Defendant has identified are party which they deem “indispensable,” that has not been joined in this case. If Defendants are considering the fact that Plaintiffs have not joined Defendants’ co-conspirator doctors in this action, “[i]t is well-established that joint tortfeasors and co-conspirators are generally not indispensable parties.” *Falken Industries, Ltd. v. Johansen*, 360 F. Supp.2d 208, 211 (D. Mass. 2005) (quoting *Casas Office Mach., Inc. v. Mita Copystar Am., Inc.*, 42 F.3d 668, 677 (1<sup>st</sup> Cir. 1994)). Therefore, AstraZeneca Aff. Def. 46 should be dismissed.

h. Failure To Mitigate Damages and Consent or Ratification

Defendants have not cited any action which Plaintiffs should have taken to minimize their damages flowing from Defendants’ actions. If Defendants mean to suggest allege that cancer patients should discontinue the use of lifesaving medications, common sense such a claim should be dismissed. AstraZeneca Aff. Def. Astra 49 should be dismissed.

**2. Affirmative Defenses Contending that Plaintiffs' Conspiracy Claims Are Barred Should Be Dismissed.**

a. Defendants Cannot Demonstrate that Plaintiffs Failed To Allege Concerted Action As Required by Cited Cases

Defendants contend that Plaintiffs' civil conspiracy claims are barred because Plaintiffs allegedly have failed to plead a concerted action. The case law relied upon by Defendants states that, "in order to state a claim of civil conspiracy, plaintiff must allege that defendants, acting in unison, had some peculiar power of coercion over plaintiff that they would not have had if they had been acting independently." *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1563 (1st Cir. 1994). An alternative cause of action for civil conspiracy requires a common design or agreement, not necessarily express, between two or more persons to perform a wrongful act and evidence of a tortious act in furtherance of the agreement. *Id.* at 1564. Defendants' contention is either that Plaintiffs have insufficiently pled their claims or there is an insufficiency of evidence as to this claim. This is not a cognizable "affirmative defense," and, as such, could also have been analyzed under Section II(D)(3) above. Regardless of whether this Court finds the argument to be a cognizable "affirmative defense," Plaintiffs are entitled to summary judgment on the issue because Plaintiffs specifically pled civil conspiracy in the TAMCC identified as the "AWP Scheme," an industry wide scheme alleging that Defendants conspired with their doctor customers (and with each other) in connection with the marketing of the spread created by inflated AWPs. Moreover, the Defendants' power of coercion is innate by virtue of the fact that they manufacture and sell the drugs which Plaintiffs need to survive and by virtue of the involvement of their co-conspirators/customers, the doctors, with whom Plaintiffs have a

relationship of trust. Therefore, Defendants should be precluded from asserting AstraZeneca Aff. Def. 24 as an affirmative defense.

b. Defendants Cannot Demonstrate that Plaintiffs' Claims Are Duplicative or Improper Under Massachusetts Law

Defendants contend that Plaintiffs' civil conspiracy claims are barred because they are duplicative under Massachusetts law. "Where the allegations of conspiracy add nothing to the underlying tort allegations, the courts have repeatedly held that the gist of such an action is not the conspiracy alleged, but the tort committed against the plaintiff." *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp.2d 344, 364 (D. Mass. 2002). In *Grant*, the plaintiff claimed that each of two security guards assaulted him and the court granted summary judgment to the defendants on his claim that they conspired to assault him. The facts before this court are very different – Defendants not only conspired in the commission of the fraud against Plaintiffs, they also conspired to conceal their conduct. Plaintiffs' conspiracy claims are not duplicative of the underlying consumer fraud claims, pursuant to *U.S. Liab. Ins. Co. v. Selman, supra*, Section II(A). Thus, AstraZeneca Aff. Def. 25 should be barred.

**3. Affirmative Defenses Contending that Plaintiffs' Claims Are Barred Because Defendants' Conduct Did Not Have Adverse Effects on Competition Should Be Dismissed.**

Defendants contend that Plaintiffs' claims are barred because their respective conduct was not intended to adversely effect competition. Pursuant to MASS. GEN. L. 93A, § 2, intent of the actor is not a prerequisite in protecting consumers from unfair competition. As such, this defense is not a cognizable defense under the Massachusetts Consumer Protection Act and therefore should be barred. Notwithstanding this fact, Defendants' fraudulent scheme and

conspiracy not only had adverse effects on competition, it turned the traditional notion of competition on its head, whereby competitors were competing not to sell at the lowest price, but to sell at the highest AWP with the largest spread/profit for their customers. Therefore, AstraZeneca Aff. Def. 38 should be dismissed.

**4. Affirmative Defenses Contending that Plaintiffs' Claims Are Barred or Limited As a Result of Issues with Damages Should Be Dismissed.**

a. Plaintiffs' Damages Are Not Too Speculative and Remote As It Will Not Be Too Difficult To Ascertain and Allocate Damages

Defendants contend that Plaintiffs' claims are barred because Plaintiffs' damages are too speculative and difficult to ascertain and allocate. This is an insufficiency of evidence allegation, tantamount to a denial, which is not a cognizable affirmative defense. (Thus, this affirmative defense could also have been analyzed under Section II(D)(3)). Sufficient evidence will be presented at trial to satisfy the *prima facie* elements of damages for all claims. Further, a "wrongdoer is not entitled to complain that [damages] cannot be measured with the exactness and precision that would be possible if the case, which he alone is responsible for making, were otherwise." *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931).

*See also Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264-65 (1946) ("Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim. It would be an inducement to make wrongdoing so effective and complete in every case as to preclude any recovery, by rendering the measure of damages uncertain. Failure to apply it would mean that the more grievous the wrong done, the less likelihood there would be of a recovery.") *Brunswick Corp. v. Spinit Reel Co.*, 832 F.2d 513, 526 (10<sup>th</sup> Cir. 1987) ("A defendant whose wrongful conduct has caused the difficulty in assessing damages cannot complain that the

damages are somewhat speculative.”). Defendants therefore should be precluded from asserting these allegations, like AstraZeneca Aff. Def. 49.<sup>10</sup>

b. Defendants Cannot Demonstrate that Plaintiffs Would Be Unjustly Enriched.

Defendants contend that Plaintiffs’ claims are barred because Plaintiffs would be unjustly enriched. In this instance, unjust enrichment requires the Defendants to demonstrate: (1) that Defendants conferred a measurable benefit upon the Plaintiffs, (2) Plaintiffs accepted services with the reasonable expectation of compensating the Defendants, and (3) Defendants provided the services with the reasonable expectation of receiving compensation from the Plaintiffs. *Mass. Cash Register, Inc. v. Contrex Systems Corp.*, 901 F. Supp. 404, 423 (D. Mass.1995); *Bolen v. Paragon Plastics*, 747 F. Supp. 103, 106-07 (D. Mass.1990); *Salamon v. Terra*, 394 Mass. 857, 859 (1985). Obviously, unjust enrichment is not an affirmative defense under the facts of this case. Moreover, Defendants cannot satisfy their burden of showing that Plaintiffs were unjustly enriched, pursuant to *U.S. Liab. Ins. Co. v. Selman, supra*, § II.A. Therefore, that portion of AstraZeneca Aff. Def. 49 should be dismissed.

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<sup>10</sup> In the *Gilbert* case, *supra*, in analyzing codefendant’s affirmative defense that the damages claimed by plaintiff were allegedly exaggerated and speculative, the court held that the codefendant’s claim was:

not an affirmative defense but a negative defense, encompassed under the general denial made by this codefendant of plaintiff’s assertion related to the damages he has suffered and, as such, must be stricken. Likewise, this is not to say that at trial, this codefendant cannot present evidence to prove that the damages suffered by the plaintiff are not as high as he alleges they are.

56 F.R.D. at 125. See *supra* Section D3.

c. Plaintiffs' Damages Should Not Be Limited by a Statutory Ceiling

Defendants contend that Plaintiffs' claims are barred because damages allegedly are limited by a statutory ceiling. MASS. GEN. L. 93A, *et seq.*, clearly reveals that damages are not limited by a statutory ceiling. There are no applicable statutory ceilings cited by Defendants in this matter which would limit Plaintiffs ability to recover damages. Therefore, AstraZeneca Aff. Def. 51 should be dismissed.

**5. Affirmative Defenses Contending that Reliance Is Required by State Consumer Protection Laws, including Those of New York and Pennsylvania, and that Plaintiffs Did Not Rely Upon Allegedly Fraudulent Statements or Conduct of Defendants Should Be Dismissed.**

Defendants contend that reliance is required by state consumer protection laws, including those of New York and Pennsylvania, and that Plaintiffs did not rely on Defendants' fraudulent statements and conduct. Under the Massachusetts Consumer Protection Act, MASS. GEN. L. 93A § 2, and the New York Consumer Protection Act, N.Y. GEN. BUS. L. § 349, however, reliance by the plaintiff is not a necessary element of plaintiff's case. *Slaney v. Westwood Auto, Inc.*, 366 Mass. 688, 703, 322 N.E.2d 768, 779 (1975) ("in the statutory action proof of actual reliance by the plaintiff on a representation is not required,..."); *Aspinall v. Philip Morris Companies, Inc.*, 813 N.E.2d 476, 486, 442 Mass. 381, 394 (2004); *Gale v. International Business Machines Corp.*, 781 N.Y.S.2d 45 (2004); and *Singh v. Queens Ledger Newspaper Group*, 770 N.Y.S.2d 99 (2003). Although reliance has been found in certain cases to be required in Pennsylvania, this is not an affirmative defense and it should not apply in this case where patients paid their AWP-based bills without any knowledge of the consumer fraud involved. At best, this argument goes to the sufficiency of Plaintiffs' proof of trial and should be a question of fact for the jury.

Therefore, AstraZeneca Aff. Def. 31 should be dismissed.

**6. Affirmative Defenses Contending that Plaintiffs' Claims Are Barred Because Defendants' Conduct Was Protected by Law Should Be Dismissed**

a. The First Amendment

The First Amendment is not implicated in any way in this matter, and it is not an “affirmative defense” to the consumer protection claims asserted herein. The First Amendment does not protect against fraudulent conduct or speech. *U.S. v. Philip Morris Inc.*, 304 F. Supp.2d 60 (D.D.C.2004). *R.A.V. v. St. Paul*, 505 U.S. 377, 388-89 (1992) (“[A] State may choose to regulate price advertising in one industry but not in others, because the risk of fraud (one of the characteristics of commercial speech that justifies depriving it of full First Amendment protection ...) is in its view greater there.”) (citations omitted). Therefore, AstraZeneca Aff. Def. 6 should be dismissed.

b. The Due Process and Ex Post Facto Clauses

Defendants affirmatively state that the Due Process and Ex Post Facto Clauses of the United States Constitution and unidentified state constitutions bar Plaintiffs’ claims to the extent Plaintiffs seek to impose liability retroactively for conduct that was not actionable at the time it occurred. Defendants fail to meet their burden of proof with respect to this claimed “affirmative defense.” Defendants have not stated what, if any, of their conduct was not actionable at the time it occurred. The Court has defined the class period for Classes 1 and 2 to be January 1, 1991 through January 1, 2005 (and through the present for Class 3). Moreover, the Due Process Clause of Fourteenth Amendment generally does not prohibit the retroactive application of civil legislation. In order for retroactive application to be prohibited, the consequences of the

retroactive application must be particularly harsh and oppressive. *U. S. Trust Co. of New York v. New Jersey*, 431 U.S. 1 (1977). Defendants have not and cannot establish that imposition of liability for their past fraudulent acts and representations is harsh or oppressive. Defendants clearly should have anticipated that liability could result from their fraudulent actions, whether a specific statute existed at the time prohibiting it or not. Additionally, if it is proper for the United States government to criminally prosecute for these past acts, then it is equally proper for consumers and TPP victims (the victims of these crimes) to hold the Defendants civilly responsible. Therefore, AstraZeneca Aff. Def. 14 should be dismissed.

#### **7. Affirmative Defenses Contending that Plaintiffs' Claims Are Barred Because Defendants' Conduct Was Justified Should Be Dismissed**

##### a. Compliance with Applicable Regulations of the Federal and State Governments

This “defense” is vague and ambiguous. No state or federal regulations condone fraud and/or violations of state consumer protection acts. Plaintiffs challenge Defendants to present in their response any legal or evidentiary support in furtherance of this claimed defense. If none is presented, summary judgment barring this defense is appropriate. Therefore, AstraZeneca Aff. Def. 12 should be dismissed.

##### b. Good Faith and Conformity with Established Industry Practice

Essentially, Defendants allege that since everyone one was doing it, how could it be a violation of law? While not a defense, the argument that “everybody does it” – *i.e.* the widespread violation of law by others – does not create a loophole for a particular Defendant’s violations of law. *Cf. Untied States v. Standefer*, 452 F. Supp. 1178, 1188 (W.D. Pa. 1978) (alleged industry practice was no defense to criminal prosecution of tax officer of corporation for

giving gratuities, including vacations, to Internal Revenue Service agent responsible for auditing corporation.) Additionally, Defendants have not pointed to any specific facts in the record establishing that a usual and customary standard industry practice existed concerning inflated AWPs, promotion of spreads and other conduct enumerated in the TAMCC such related to pricing that they adhered to some purported customary and reasonable standard practices. Therefore, AstraZeneca Aff. Def. 9 should be dismissed.

#### **8. Prior Settlements**

No settlement of Plaintiffs' claims has occurred such that there can be any claim of a bar by res judicata, collateral estoppel or double recovery. Similarly, there can be no claim of release, settlement, accord and satisfaction or set off for amounts already paid to persons other than Class Plaintiffs. No Defendant has submitted any evidence of any other settlement which would impact upon this case. Therefore, AstraZeneca Aff. Defs. 5, 8 and 50 should be dismissed.

#### **III. CONCLUSION**

For the reasons stated above, Class Plaintiffs request that the motion be granted.

DATED: March 15, 2006

By /s/ Steve W. Berman

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**CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE**

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on March 15, 2006, I caused copies of **CLASS PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON DEFENDANTS' AFFIRMATIVE DEFENSES** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

Steve W. Berman